DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

D1339B

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

September 11, 1997

WARNING LETTER
CHI-47-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Harry L. Crisp II, President
Marion Pepsi-Cola Bottling Co.
Old Route 13 West
P.O. Box 1070
Marion, IL 62959

Dear Mr. Crisp:

On August 18-21, 25, 1997, the Food and Drug Administration (FDA) conducted an inspection of your beverage and water bottling plant. FDA Investigator Frederick W. French confirmed that your firm bottles and sells filtered municipal drinking water under the "Crisp 'n Clear" and "Natural Springs" labels.

The FDA, after review of your labels for these products, finds them misbranded under Section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

> The labels for "NATURAL SPRINGS DRINKING WATER**" collected during the inspection are misbranded under Section 403(g)(1) of the Act in that the bottled water is represented as spring water for which a standard of identity has been prescribed by regulation and the product fails to meet the definition of spring water (Title 21, Code of Federal Regulations (21 CFR), Section 165.110(a)(2)(vi)).
>
> "CRISP 'n CLEAR DRINKING WATER" and "NATURAL SPRINGS DRINKING WATER" are misbranded within the meaning of Section 403(a)(1) and 201(n) of the Act in that their labels imply that the water is from natural springs when it is actually from a municipal water source. The above mentioned bottled water products did not bear the required statement "from a community water system," or "from a municipal source." This labeling statement is required when bottled water comes from a community water system and has not been treated to meet the definitions in 21 CFR Section 165.110(a)(2)(iv) and (a)(2)(vii), as prescribed in 21 CFR 165.110(a)(3)(ii).

You should take prompt action to correct these deficiencies. Failure to promptly correct these label deficiencies may result in regulatory action being initiated by FDA without further notice. These include seizure and injunction.

We have the following comments regarding deviations from the Current Good Manufacturing Regulations (CGMP), 21 CFR Part 129 - Processing and Bottling of Bottled Drinking Water.

1. Your firm fails to record and maintain production codes of finished products and fails to maintain all required records for at least two years. 21 CFR Sections 129.80(e) and 129.80(h)

2. Your firm fails to conduct bacteriological testing of containers and closures prior to filling and sealing and fails to conduct finished product testing. 21 CFR Sections 129.80(f) and 129.80(g)

3. You firm fails to conduct finished product testing prior to release for distribution of the retail units of bottled drinking water. 21 CFR Section 129.80(g)(1)

4. Your firm fails to conduct annual chemical, physical, and radiological testing of representative samples of each type of bottled drinking water produced and distributed. 21 CFR Section 129.80(g)(2)

Please notify this office in writing within 15 days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason and the time within which the corrections will be completed.

Your reply should be directed to the attention of Jerome Bressler, Assistant District Director for Compliance.

Sincerely,

/S/

Raymond V. Mlecko
District Director

Enclosure